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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,344	01/09/2006	Akihiko Takeuchi	049441-0141	2707
22428 7590 06/18/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
MELLER, MICHAEL V				
ART UNIT		PAPER NUMBER		
1655				
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06/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,344

Applicant(s)

TAKEUCHI ET AL.

Examiner

Michael V. Meller

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 and 24-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 17, 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 12 and 17 in the reply filed on 4/10/2007 is acknowledged. The traversal is on the ground(s) that applicant submits that Groups I and II have in common the blood pressure lowering activity of the claimed materials. This is not found persuasive because the claimed subject matter does not have a special technical feature as addressed in the restriction requirement since the method of claim 12 is known as is evidenced by the reference cited. Further, since claim 13 encompasses "prevention" this clearly does not read on a "mammal suffering from hypertension" since prevention, prevents what has to be treated, i.e. hypertension. In other words, preventing hypertension, the patient does not have to suffer from hypertension for it to read on claim 13 whereas in claim 12 the patient clearly has to suffer from hypertension. A reference that anticipates prevention does not anticipate "suffering from hypertension".

Accordingly, claims 13-16, 24-36 are withdrawn from further consideration as being drawn to non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 12, 17, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 173741/1992 (applicant submitted this) in view of Babish et al. (US 7279185- already of record).

JP teaches that a hops extract is used to treat hypertension, see whole reference especially page 1, the claims. JP does not teach that the hops extract is specifically a isohumulone.

Babish teaches that alpha acids (such as isohumulones) are compounds isolated from hops, see col. 5, lines 5-20.

The hops extract of JP are not specifically defined as being isohumulones, but since Babish establishes that isohumulones are compounds isolated from hops then it clearly would have been within the purview of the skilled artisan to use isohumulones in

the process of JP with the expectation of success since Babish establishes that isohumulones are well known to be hops extracts and since Babish yields such beneficial results using such isohumulones.

Applicants in their response filed 4/8/2009 argued that the term "hop extract" does not necessarily include isohumulones. In fact hops extract does include all extracts of hops which do include isohumulones. It is true that all hops extracts are not isohumulones but this is not a USC 102 rejection thus the argument is without merit. Babish establishes that isohumulones are clearly hops extracts were clearly known at the time the invention was made to be to be hops extracts. The 35 USC 103 rejection was made to show that a person having ordinary skill in the art at the time the invention was made would have known very clearly that hops extracts do in fact include isohumulones. Applicants themselves disclose using hops extracts and more particularly isohumulones, but even applicants disclosed and previously claimed hops extracts. Thus, it was clearly well known to one having ordinary skill in the art at the time the invention was made that hops extract clearly includes isohumulones and clearly it would have been well within the purview of the ordinary artisan to employ isohumulones as well as other well known hops extract in the method of JP at the time the invention was made.

Applicant next argues that Jp teaches a multiple use of compounds including hops. This is noted but claims 12, 17 and 37 are not limited to hops. As for claims 38

and 39. There is nothing in applicant's specification which defines what applicant means but "consisting essentially of", thus the term is non limiting.

MPEP 2111.03 states:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating).

Thus, the claims can still be interpreted as reading, "comprising".

Since there does not exist a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

Thus, applicants comments concerning using isomerized hops extracts alone are without merit. There is nothing in the claims to exclude the other ingredients.

Jp does not have to mention the isomerized hops extract since this is a 35 USC 103 rejection and Babish establishes what is discussed above, that one having ordinary

skill in the art at the time then invention was made would have known that hops extract clearly includes the well known isohumulones which have very well documented beneficial properties. In fact applicant has disclosed using hops extract as well as isomerized hops extract making it clear that even applicant used either one, making them functional equivalents.

Jp **never** states that all five components **must** be used to achieve its effects. Applicant argues that no blood pressure lowering activity is associated with the hop extract, but this is why this rejection is a 35 USC 103 rejection and not a 35 USC 102 rejection. Babish provides this motivation for the above reasons and for the reasons of record.

3. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Babish does not teach that the isohumulones are used to lower blood pressure, but as noted above this is **not a 35 USC 102 rejection** and Babish was cited to show that hops extract refers to the well known isohumulones which would have been well within the purview of the ordinary artisan such as applicants themselves who originally claimed and disclosed using hops extracts which were not all

isohumulones or isomerized hops extract. In other words, applicants themselves used both hops extracts and isohumulones which proves that one of ordinary skill in the art at the time the invention was made would have used either extract, thus making applicant's arguments moot.

Applicants argue that since the isohumulones of Babish were used for inflammation why would one use the isohumulone of Babish in the method of JP but this has been addressed over and over above. Babish provides the common understanding that hops extract at the time the invention was made clearly included the well known isohumulones and such isohumulones had a desirable effect. Even applicants themselves have used both hops extract and isomerized hops extract in their own disclosure. Babish was not cited for its use but for the fact that isohumulones are well known hops extracts.

Applicants next argument is that the examiner is trying to eliminate all of the extracts of JP this is simply not true. Jp teaches that hops extract were used to treat the claimed hypertension. The examiner has very clearly established that Babish establishes that hops extract at the time the invention was made clearly included the well known isohumulones and such isohumulones had a desirable effect. Even applicants themselves have used both hops extract and isomerized hops extract in their own disclosure.

Lastly applicants argue that Jp does not teach the claimed hypertension. This is clearly without merit as even claim 1 of JP recites "treatment of hypertension" .

Thus, the rejection is proper and is maintained for the above reasons and for the reasons of record.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655

